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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,178	10/28/2003	J. Daniel Rauerson	MED0065	4287
33941	7590	05/18/2009	EXAMINER	
FOX Rothschild LLP			VU, QUYNH-NHU HOANG	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/695,178	<b>Applicant(s)</b> RAULERSON ET AL.
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 24 March 2009.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 34-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 34-38 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/12/08

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

Amendment filed on 3/24/09 has been entered.

Claims 34-38 are present for examination.

Claims 29-33 are withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "portion of the proximal end portion extend through the hub member" is vague.

Which portion of the proximal end of 1st or 2<sup>nd</sup> catheter or 1<sup>st</sup> or 2<sup>nd</sup> extension tube?

The limitation "the proximal end portions" in lines 12 of claim 24. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

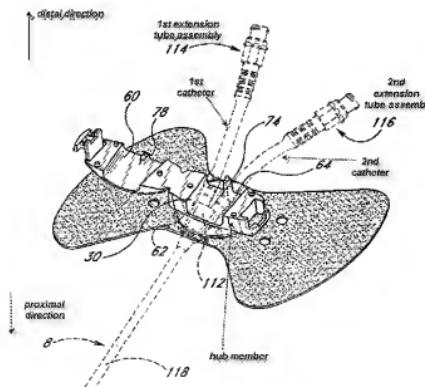
Claims 34-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Bierman et al. (US 6,663,600)

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Bierman discloses a multiple catheter assembly comprising: a first catheter; a second catheter; a first and second extension tube 114, 116; a hub member 20 adapted to be releasably attachable to and around the first and second proximal end.

*It has been held that the recitation that the hub member is "adapted to/capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.*

*Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. after catheter implantation and subcutaneous tunneling... to respective medical devices, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).*



#### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al. (US 5,947,953) in view of Raulerson (US 4,037,599) or Bierman et al. (US 6,582,403).

Ash discloses a multiple catheter assembly, comprising:

a first catheter 26 having a first distal end region and a first proximal end region joined by a first intermediate section;  
a second catheter 30 having a second distal end region and a second proximal end region joined by a second intermediate section;  
first and second extension tube assemblies 84, 90 having first and second distal end portions respectively associated with the first and second proximal end regions of the first and second catheters; and

a hub member 24 adapted to be releasably attachable to and around the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof, after catheter implantation and subcutaneous tunneling and at a site selectable by the practitioner, such that portions of the proximal end portions extend through the hub member and proximally beyond the proximal end thereof to be connected to respective medical devices.

The hub member 24 of Ash does not adapted to be releasably attachable around the first and second proximal end region of the first and second catheters.

Raulerson discloses a catheter device with a separate hub 18 adapted to be releasably attachable to and around the first and the second proximal end regions distally of the proximal end.

Bierman discloses a catheter device with a hub member adapted to be releasably attachable, as shown in Fig. 27.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Ash with the releasably hub, as taught by Raulerson or Bierman, in order to attach or release the hub to the tubes and the patient in a flexible moveable manner.

*It has been held that the recitation that the hub member is "adapted to/capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.*

*Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. after catheter implantation and subcutaneous tunneling... to respective medical devices, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).*

Regarding claims 35, wherein the cross- sectional shapes of the first and second proximal end regions is circular (col. 7, lines 30-38), and the cross- sectional shapes of the first and second distal end portions of the first and second extension tubes is circular is very well-known in the catheter art.

Regarding claim 36, wherein the cross- sectional shapes of the first and second intermediate sections of the first and second catheters is semicircular (Fig. 4F), and the first and second catheters have transition sections between the circular cross-sectional shapes of the first and second proximal and distal end regions and the semicircular cross-sectional shapes of the first and second intermediate sections.

Regarding claim 37, wherein the first and second intermediate sections of the first and second catheters are splittably joined to each other by element 46.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al. (US 5,947,953) in view of Raulerson (US 4,037,599) or Bierman et al. (US 6,582,403) and further in view of Cazal (US 5,800,414).

Ash et al. in view of Raulerson/ Bierman discloses the invention substantially as claimed.

Ash et al. in view of Raulerson/Bierman discloses the first and second intermediate sections of the first and second catheter are splittably joined to each other by member 46. Ash et al. in view of Raulerson does not disclose the splittably joined to each other by adhesive.

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Cazal discloses a similar device, in which the first and second catheters are splittably joined to each other by adhesive 14 or 20.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Ash et al. in view of Raulerson/Bierman, with an adhesive, as taught by Cazal, in order to join the two catheters.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/974,267.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they device of instant claims are fully disclosed and covered by the claims in the copending application claims.

As noted that, claims 1-37 does not include the hub or an initially separate hub. However, the Applicant admitted that the hub 150 may be omitted is common sense or well-known in the art (see para 0036 of Specification or para 0050 of Application 10/974267). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to the releasable hub, since it has been

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held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 34-38 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763